

Policy and Procedure		
SUBJECT: Determination of a First Tier, Downstream and Related Entity (FDR)	DEPARTMENT: Regulatory Compliance, Risk Management and Government Affairs	
ORIGINAL EFFECTIVE DATE: 03/13	DATE(S) REVIEWED/REVISED: 12/13, 03/14, 12/15, 09/16, 12/17, 09/18, 05/19, 04/20	
APPROVED BY: Chief Compliance and Risk Officer	NUMBER: RA 68	PAGE: 1 of 3

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All Medicare First Tier, Downstream, and Related Entities (FDRs)

POLICY:

In accordance with The Centers for Medicare and Medicaid Services (CMS) guidelines Company contracts and delegates to several First Tier, Downstream, and Related Entities (FDRs), to provide Medicare Advantage functions on behalf of Company. These FDRs meet CMS’ definition of a “core” function.

DEFINITION:

1. **“Audit”** is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.
2. **“Delegated Entity”** is an FDR that is contracted with Company Medicare Advantage Plans (MAP) and performs a function on behalf of MAP.
3. **“FDR”** means First Tier, Downstream or Related Entity. **“First Tier Entity”** is any party that enters into a written arrangement, acceptable to CMS, with Company to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. **“Downstream Entity”** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between Company and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. **“Related Entity”** means any entity that is related to Company by common ownership or control and:
 - (1) Performs some of Company management functions under contract or delegation;
 - (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
 - (3) Leases real property or sells materials to Company at a cost of more than \$2,500 during a contract period.
4. **“Monitoring Activities”** are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

PROCEDURE:

Company’s Medicare Advantage Plans uses the criteria below to help determine if a FDR meets the definition of a delegate for “core” functions (see below for possible “core” functions):

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APPROVED BY: Chief Compliance and Risk Officer	NUMBER: RA 68	PAGE: 2 of 3

- Whether the function is something Company is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance
- To what extent the function directly impacts enrollees
- To what extent the delegated entity has interaction with enrollees, either orally or in writing
- Whether the delegated entity has access to beneficiary information or personal health information
- Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from the Company
- The extent to which the function places the delegated entity in a position to commit health care fraud, waste or abuse (FWA); and
- The risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA.

Examples of “core” functions that relate to Company or any Medicare Parts C and D contracts are but not limited to:

- Sales and marketing
- Utilization management
- Quality improvement
- Applications processing
- Enrollment, disenrollment, membership functions
- Claims administration, processing and coverage adjudication
- Appeals and grievances
- Licensing and credentialing
- Pharmacy benefit management
- Hotline operations
- Customer service
- Bid preparation
- Outbound enrollment verification
- Provider network management
- Processing of pharmacy claims at the point of sale
- Negotiation with prescription drug manufacturers and others for rebates discounts or other price concessions on prescription drugs
- Administration and tracking of enrollees’ drug benefits, including TrOOP balance processing
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs

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APPROVED BY: Chief Compliance and Risk Officer	NUMBER: RA 68	PAGE: 3 of 3

- Entities that generate claims data and
- Health care services

Once Company determines that an entity meets the qualifications as an FDR, a pre-delegation audit is performed if applicable, and is run through the excluded provider check lists before the entity can be formally delegated. In addition, Company executes a formal delegation agreement compliant with CMS guidelines and regulations. Company continually requires self-monitoring of our delegated entities and will also audit delegates based on an annual risk assessment, see below for further details.

Company requires delegated entities to fill out a self-assessment annually. Company also performs an annual risk assessment on all delegated entities to determine the roadmap for how Company will provide specialized training, applicable audits and level of oversight for all delegated entities.

REFERENCES:

Providence Medicare Advantage Plans Compliance Program, CFR §422.503(b)(4)(vi), §422.504(i), §423.504(b)(4)(vi) and §423.505(i), Chapter 9 of the Medicare Prescription Drug Manual, Chapter 21 of the Medicare Managed Care Manual, Compliance Program Guidelines